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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,784	01/28/2002	Daniel Henry Densham	GJE-78	7070

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/937,784**

Applicant(s)  
**Densham**

Examiner  
**Arun Chakrabarti**

Art Unit  
**1634**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jan 29, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 7-21 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/937,784.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action

Art Unit: 1634

## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I, corresponding to claims 7-20 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that sensor chip of claim 21 is not disclosed by WO 99/05315 and therefore claims 7-21 be considered and examined together. This has been found persuasive and all pending claims 7-21 are hereby being examined together.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 14 are rejected as indefinite because the instantly claimed method lacks a final process step that clearly relates back to the preamble. For the method of claims 7 and 14, the preambles of the instantly claimed methods are drawn to a method for sequencing a polynucleotide while the final process step is that of detecting the interaction between the enzyme and a nucleotide on the target polynucleotide and it is not clear if the goal of the preamble i.e., for sequencing a polynucleotide is achieved or not and if achieved, in what step it is achieved, and it

Art Unit: 1634

is thus unclear as to whether the instantly claimed methods are drawn to methods for sequencing a polynucleotide or rather detecting the interaction between the enzyme and a nucleotide on the target polynucleotide. Method claim requires a last step or phrase in the last step that states the accomplishments of the goals for the method which were stated in the method's preamble. Claims 7 and 14 lack such a last step and are confusing because the additional method step is not sufficiently set forth. While minute details are not required in method claims, at least the basic steps must be recited in a positive, active fashions. See Ex parte Erlich, 3 USPQ2d1011, p.1011 (Bd. Pat. Applicant. Int. 1986). It is suggested that an amended claim more clearly describing the intended steps be submitted.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 1634

5. Claims 7, 13, 14, and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Crute (U.S. Patent 5,958,696) (September 28, 1999).

Crute teaches a method (Abstract), comprising the steps of:

(I) reacting a target polynucleotide with a helicase and/or a primase enzyme, under conditions suitable for enzyme activity (Figures 1A-C and 2 and Examples 2-4); and

(ii) detecting the interaction between the enzyme and a nucleotide on the target polynucleotide, by measuring radiation (Figures 3-6, and Examples 2-4 and claims 1-10).

Crute inherently teaches a method and a sensor chip comprising a helicase enzyme, a primase enzyme, or both a helicase enzyme and a primase enzyme,, wherein the enzyme is immobilized on a solid support (Figure 1, Step B).

With regard to the preamble limitations, it is noted in MPEP 2111.02 that "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Although Crute discloses only a quantitative solid phase helicase assay and not the method for sequencing a polynucleotide, this rejection is based on the fact that method steps of Crute are exactly same as the claimed invention as described above and therefore the process steps or structural limitations are able to stand alone and thereby meets the requirements of the instant claims because a preamble (method for sequencing a polynucleotide in this case) is generally not accorded any patentable weight where it merely recites the purpose of a process.

Art Unit: 1634

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-12, and 15-19 are rejected under 35 U.S.C. 103(a) as being obvious over Crute

(U.S. Patent 5,958,696) (September 28, 1999) in view of Densham (PCT International

Publication Number WO 99/05315) (February 4, 1999).

Crute teaches the methods and sensor chip of claims 7, 13, 14, and 20-21 as described above.

Crute does not teach the method wherein the radiation is electromagnetic and the detection, of the interaction between the enzyme and a nucleotide on the target polynucleotide, step comprises using surface plasmon resonance and nuclear magnetic resonance.

Densham teaches the method wherein the radiation is electromagnetic and the detection, of the interaction between the enzyme and a nucleotide on the target polynucleotide, step comprises using surface plasmon resonance and nuclear magnetic resonance (Page 4, line 10 to page 5, line 14 and claims 15-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time

Art Unit: 1634

the invention was made to combine and substitute the method wherein the radiation is electromagnetic and the detection, of the interaction between the enzyme and a nucleotide on the target polynucleotide, step comprises using surface plasmon resonance and nuclear magnetic resonance of Densham in the method of Crute since Densham states, "Surface plasmon resonance (SPR) spectroscopy is a preferred method, and measures the properties of a solution by detecting the differences in refractive index between the bulk phase of the solution and the evanescent wave region. Incident monochromatic light is reflected at a specific angle off a solid optical surface on the opposite side to a sample under study (Page 4, lines 25-31)" Moreover, Densham states, "Nuclear magnetic resonance (NMR) spectroscopy is another preferred method, and measures the magnetic properties of compounds (Page 5, lines 3-5)." An ordinary practitioner would have been motivated to combine and substitute the method wherein the radiation is electromagnetic and the detection, of the interaction between the enzyme and a nucleotide on the target polynucleotide, step comprises using surface plasmon resonance and nuclear magnetic resonance of Densham in the method of Crute, in order to achieve the express advantage, as noted by Densham, of surface plasmon resonance (SPR) spectroscopy which is a preferred method, and measures the properties of a solution by detecting the differences in refractive index between the bulk phase of the solution and the evanescent wave region in which the incident monochromatic light is reflected at a specific angle off a solid optical surface on the opposite side to a sample under study, and of nuclear magnetic resonance (NMR) spectroscopy which is another preferred method, and measures the magnetic properties of compounds.

Art Unit: 1634

***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

**Arun Chakrabarti  
Patent Examiner  
Art Unit 1634  
February 12, 2003**

*Arun K. Chakrabarti*  
**ARUN K. CHAKRABARTI  
PATENT EXAMINER**